

Center for Military Biomaterials Research: Focus on New Materials for Trauma Technology

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SUMMARY

The Center for Military Biomaterials Research (CeMBR) has been created as a catalyst to develop breakthrough products specifically designed for military healthcare needs. CeMBR's initial programs focus on combat wound care and protection of soldiers from chemical and biological agents. CeMBR is building a network of industrial, academic and military partners to conduct rapid development of biomaterial-based products. CeMBR is focused on meeting the needs of the military not only for these products but also for education to understand and better utilize the emerging technologies.

Introduction

The Center for Military Biomaterials Research (CeMBR) is a new program of the New Jersey Center for Biomaterials. CeMBR's mission is to create a network among academia, industry and the military that provides rapid and effective pathways for the identification, development and utilization of biomaterial-based technologies and products for the military's health care needs. The initial, principal focus of CeMBR is on biomaterials for combat casualty care.

The impetus for the founding of CeMBR comes from a study of the U.S. Army's need to understand and take full advantage of the emerging biomaterial technologies and products. This is delineated in a 2001 study by the National Academies of Science (NAS), titled "Opportunities in Biotechnology for Future Army Applications," [1], also known as the "BAST Report." The recommendations of this NAS study are: that the Army needs to partner with the existing biomedical research establishment; must have technical professionals capable of translating biomedical findings into engineering practice; and should study the potential impact of biomedical research on future military operations. CeMBR has been designed to provide the Army and other services with the means to meet these recommendations. CeMBR's first military partner is the Telemedicine and Advanced Technology Research Center (TATRC), a unit within the US Army Medical Research and Materials Command. As CeMBR's activities mature, it will reach out to the other military services.

Development of medical devices based on new biomaterials is extraordinarily complex and only a broadly based research and development organization with strong academic ties can bring together all of the science and engineering needed for a focused biomaterials development effort. Expertise is required in materials science, synthetic organic chemistry, polymer chemistry, surface chemistry and physics, pharmaceuticals, immunology, tissue engineering, biochemistry, medicine, and mechanical and biomedical engineering. Additionally, there is a intricate set of regulatory requirements that must be met to bring a biomaterial-based product to commercialization. Because CeMBR is a program within the framework of the established New Jersey Center for Biomaterials, CeMBR already has access to over 60 associated faculty members at Rutgers -

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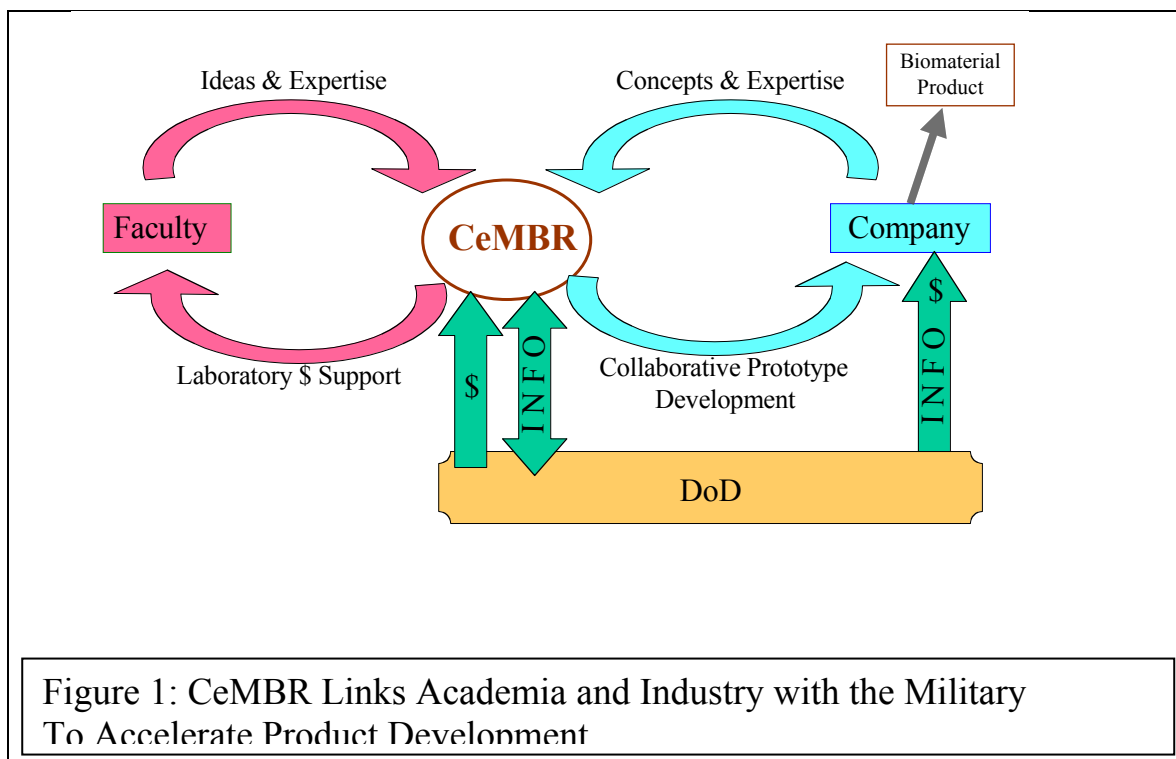
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the State University of New Jersey, the University of Medicine and Dentistry of New Jersey, and the New Jersey Institute of Technology, who can provide much of the required expertise. In addition, CeMBR has attracted faculty from other leading research universities around the country who further enhance its capabilities to meet the military's needs.

Business Model

CeMBR has adopted a “market driven” business model [2,3] with three core functions: 1) project management, 2) applied research and product development, and 3) education for the military. CeMBR will facilitate the development of industrial prototypes that are already in the product pipeline to reach commercialization in a form that meets the Army's product specifications. This means working with industrial partners to advance their technologies through development contracts that take the product through the successive stages from the laboratory to production. CeMBR has also been asked by the military to review underutilized intellectual property already funded and owned by the Department of Defense so that the potential value of these concepts can be realized. In cases where there is no available enabling technology or industrial prototype product to meet a certain military requirement, CeMBR will conduct applied research programs to develop the necessary technology. As recognized in the BAST Report, the military must build its internal capabilities to act on emerging opportunities in the biomaterials field. Because CeMBR is part of an academic partnership organization, it has in place the educators to bring the appropriate training to the military.

To accelerate product development so that biomaterial technologies can be moved quickly to battlefield applications, two cycles of interactions will be linked through CeMBR (Figure 1).



In one cycle, product requirements defined by the military will be brought to the associated faculty to obtain their best ideas and expertise. Funding and support from the Department of Defense will flow to the faculty to drive this. Simultaneously, in a second cycle, product concepts and commercial expertise at associated industrial partner companies will be linked to the military's requirements so as to create collaborative prototype development. Hence, CeMBR will facilitate the flow of biomaterial product concepts from the faculty and the industrial partners who can commercialize these concepts. Prototype products that result from these interactions will be brought to the military to gain funding and support for later stages of product development that include pre-clinical and clinical trials.

The key to success of this linked process is an effective network of industrial and military partners. Already, CeMBR has attracted the interest of several companies and is establishing a series of individual industrial partnerships. Military organizations that are already working with CeMBR include TATRC, the U.S. Army Medical Research Institute of Chemical Defense, the U.S. Army Institute of Surgical Research, the U.S. Army Research Institute of Infectious Disease, and Picatinny Arsenal. Additional partners will be sought based on the specific needs of the military as they are identified.

The management structure of CeMBR has been set up to ensure that all parts of the network are active participants. The executive committee is composed of Professor Joachim Kohn, the principal investigator, Professor David Devore, the chief operating officer, Professor Bozena Michniak, chair of the Commercialization Advisory Board, Professor Michael Jaffe, chair of the Scientific Advisory Board, and Carole Kantor, associate director of the NJ Center for Biomaterials. The Commercialization Advisory Board has members from the military, industry (including small-cap, mid-cap and large-cap companies) and academia, and also includes experts in patent law, licensing and technology transfer, business development and FDA regulatory requirements.

Federal funding for CeMBR is coordinated through TATRC. For the first two years of operations, CeMBR has received \$2.5 million and it has requested \$6.8 million for the third year in order to establish a pipeline of diversified biomaterial products that can be brought to the military market in a time frame of two to seven years. It is anticipated that the development costs for these products will be substantial, and hence, products must find dual use in the larger, civilian market in order to justify the investments required.

Identifying Military Needs

The first, and most critical, objective of CeMBR is to establish the specific needs of the military for biomaterial-based products. This is being accomplished through a collaboration with the National Academies of Science's National Materials Advisory Board (NAS/NMAB), which began with a "Biomaterials Science and Technology Roadmap Workshop" held in February, 2004. Participants in the workshop included 15 senior military representatives, 27 senior research and business managers from industry (Table 1), and 40 research faculty members in science, engineering and medicine from several universities around the country. Funding for the Workshop was provided by TATRC. The participants met for three days to identify the major biomaterial-related needs of the military. The NAS/NMAB has assembled an expert committee, chaired by James Anderson, MD, PhD, of Case Western Reserve University and the NAS Institute of Medicine, to create a report based on the Workshop. This "roadmap" document, which will provide a coordinated set of recommendations to expedite military acquisition of biomaterials-related healthcare products, will be available in the summer of 2004.

**Table 1
Industry Participants in the Biomaterials Roadmap Workshop**

<ul style="list-style-type: none"> • Advanced Ceramics Research – Tucson AZ • BioCure Inc. – Norcross GA • Celgene, Inc. – North Brunswick NJ • Center for Biomaterials and Advanced Technology, Ethicon Inc. – Somerville NJ • Corium International Inc. – Redwood City CA • ECI Biotech – Worcester MA • FMC Corporation – Philadelphia PA • Hale & Dorr – Princeton NJ 	<ul style="list-style-type: none"> • Johnson & Johnson Wound Management – Somerville NJ • Laureate Pharma LP – Princeton NJ • LifeCell Corporation – Branchburg NJ • Ortho Clinical Diagnostics – A Johnson & Johnson Company – Raritan NJ • Osteotech, Inc. – Eatontown NJ • Polymerix Corporation – Piscataway NJ • Tepha, Inc. – Cambridge MA • TyRx Pharma, Inc. – New Brunswick NJ • Vectramed Inc. – Princeton NJ • Vincogen Inc. – North Brunswick NJ
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The Roadmap Workshop participants identified four major areas of importance to the military: 1) wound care, 2) agent delivery, 3) tissue regeneration, and 4) sensors and diagnostics. Biomaterials for wound care may lead to products that ultimately provide wound closure and limb stabilization, including dressings that stop bleeding while delivering antibiotics and pain relief. Agent delivery includes such biomaterial applications as vaccine adjuvants and barrier creams providing prophylaxis for exposure to biological and chemical agents. Tissue regeneration is a broad area, involving neural, vascular and orthopedic applications; examples include conduits to channel regrowth of severed nerves, biomaterials with extracellular matrix components for nerve regeneration, resorbable anti-thrombogenic implantable vascular devices, antibiotics in bone grafts, and weight bearing bone substitutes that remodel into the host bone. Such products are anticipated to have several major effects, including saving limbs, restoring function, and enabling faster return of warfighters to active duty.

Biomaterials Research Programs

In keeping with the objective to rapidly advance products, CeMBR has already initiated an applied research program that targets areas known from the BAST Report to be essential to the Army's needs. The first project is being conducted by BioCure, Inc. (Norcross, GA) on a fast-polymerizing, spray-on wound dressing for battlefield use. The initial version of the dressing will provide a robust, abrasion resistant, adhesive dressing that will be applicable to complex anatomical geometries. Later versions of the dressing will include drug delivery for treatment of pain, infection and bleeding.

The second project is being conducted by Professor Bo Michniak at UMDNJ on a human skin model for evaluating protection from chemical warfare agents. Professor Michniak has begun a collaboration with Dr. Ernest Braue, Jr., U.S. Army Medical Research Institute of Chemical Defense, Aberdeen Proving Ground, MD, to identify chemical warfare agents that are of the greatest concern to the military and to select simulants for these agents that mimic their chemical and physical behavior so as to enable testing and development of predictive chemical information. In addition, CeMBR is working with the U.S. Army Medical Research Institute of Infectious Diseases to develop projects directed at vaccines and drug delivery for defense against major biological weapons threats such as anthrax and botulinum.

Once the NAS' Roadmap Report is complete, CeMBR's Commercialization Advisory Board will begin to review proposals for new projects and solicit industrial partners so as to target the most critical military needs. By the third year of funding, CeMBR will launch educational programs developed with its military advisors to enable the military to better understand and utilize biomaterial technologies. Also, CeMBR will begin a review of the military's "orphaned" intellectual property in order to bring valuable concepts back into the product development cycle.

Intellectual Property and Funding

There are at least three sources of intellectual property (IP) that CeMBR will use to create value for the military: University IP, Industrial IP, and Military (DoD) IP. CeMBR will match the IP to military healthcare needs and create partnerships with the owners of the IP to advance the technologies to meet military requirements. Whenever appropriate, CeMBR will develop licensing agreements for the IP and may assist in forming spin-out companies to produce the products. This will enable funds to flow back to the inventors of the IP as well as providing funding to CeMBR in the form of contracts or IP licenses.

CeMBR will allocate its funds to support industrial partners as they develop their prototype products to reach rapid commercialization. CeMBR will also allocate funds to support research or development contracts for university faculty members who are working on new biomaterials science and technology that will be required to meet military requirements, and also for development of their existing advanced pre-commercial prototypes. CeMBR funds will also be allocated for development and delivery of educational programs on biomaterials for the military.

CeMBR's organization and network are in place and growing. In March, 2005, CeMBR will move into its new \$14 million building on the Rutgers campus in Piscataway, which will provide laboratory, clean room, pilot scale-up and office facilities (Figure 2).



Figure 2. CeMBR's New Home in the Life Sciences Building at Rutgers

Status

CeMBR's management team is in place and the Commercialization Advisory Board has convened. Active, enthusiastic support has come from several U.S. Army organizations, including Picatinny Arsenal, US Army Medical Research Institute of Chemical Defense, US Army Medical Research Institute of Infectious Disease, and US Army Institute of Surgical Research. It is anticipated that CeMBR will grow its military interactions to include the other service branches and CeMBR will begin to operate as a national center, bringing in the leading companies and university faculty in the biomaterials field. Because the goal of CeMBR is rapid commercialization and utilization of biomaterials-based products by the military, CeMBR has also initiated discussions with the US Food and Drug Administration so that FDA requirements will be defined at the onset of each CeMBR program to help speed the development process. The Biomaterials Roadmap Workshop will be an annual process in which the needs of the military are reviewed in detail, along with all product development and research programs; these programs will be modified or new ones initiated as required to address the most current needs.

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